

Contents: Corrective and Preventive Action

Effective Date: December 2003

Point of Contact: Quality Management Office

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Shipping Violation Events and Causal Factor Analysis Chart Example

Forms

Supplier Corrective Action Request (SCAR) Form

Training Requirements and Reporting Obligations

This subject area does not contain training requirements.

This subject area does not contain reporting obligations.

References

ACC-INV 103, System Safety Development Center User's Guide and Cut Sheets for The Management Oversight and Risk Tree

Causal Analysis Pilot Training Course for BNL (Battelle Memorial Institute, April 25, 2001)

Causal Factors Analysis Training, Module 4: The Five Whys Technique, April 2001

Critiques Subject Area

DOE-76-45/14 SSDC-14 Revision 2, Events and Causal Factors Charting. May 1993

DOE-NE-STD-1004-92, DOE Root Cause Analysis Guidance Document, February 1992

DOE Office of Performance Excellence, Process Improvement Guide: Taking the Mystery Out of P.I.

Environment, Safety, Health and Quality (Tier I) Inspections Subject Area

Environmental Assessments Subject Area

ES&H Standard 1.1.1, Price-Anderson Amendments Act Compliance Validation and Noncompliance Reporting Program

ES&H Standard 1.2.1, Corrective Action Management and Tracking for External and Internal Assessments

Family Assessment Tracking System (F-ATS)

Hazard Analysis Subject Area

Integrated Assessment Subject Area

Internal Controlled Documents Subject Area

Investigation of Incidents, Accidents, and Injuries Subject Area

Lessons Learned Subject Area

Nonconformances, Identifying and Reporting Subject Area

Occurrence Reporting and Processing System (ORPS) Subject Area

OAMAG 02 Deceter Division Deat Course Dropadure

WAIVITO-US, REACTOR DIVISION ROOF Cause Procedure

Radiological Awareness Reports Subject Area

TapRooT® The System for Root Cause Analysis, Problem Investigation, and Proactive Improvement by Mark Paradies and L. Unger (System Improvements Inc., 2000)

Standards of Performance

Managers shall establish, implement, and track appropriate actions to correct weaknesses in performance and areas for improvement.

Management System

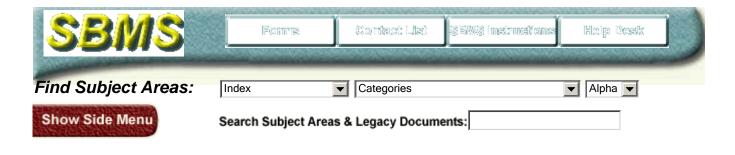
This subject area belongs to the **Quality Management** management system.

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Introduction: Corrective and Preventive Action

Effective Date: December 2003

Point of Contact: Quality Management Office

Various SBMS documents require that corrective actions be developed in order to prevent recurrence of identified issues of concern. Effective corrective actions are based on causes that have been identified through a systematic (causal analysis) process. This subject area includes a graded approach for conducting causal analysis using suggested methodologies. The graded approach is based on the significance associated with the issue of concern, or as required by the governing subject area. Examples of SBMS documents that require corrective actions to be developed include:

Critiques Subject Area

Environment, Safety, Health and Quality (Tier I) Inspections Subject Area

Environmental Assessments Subject Area

ES&H Standard 1.1.1, Price-Anderson Amendments Act Compliance Validation and Noncompliance Reporting Program

ES&H Standard 1.2.1, Corrective Action Management and Tracking for External and Internal Assessments

Integrated Assessment Subject Area

Investigation of Incidents, Accidents, and Injuries Subject Area

Nonconformances, Identifying and Reporting Subject Area

Occurrence Reporting and Processing System (ORPS) Subject Area

Radiological Awareness Reports Subject Area

This subject area provides Laboratory-wide procedures for developing corrective and preventive actions to address identified issues of concern based on causal analysis. An issue of concern may be a nonconformance, assessment finding, one significant event, a combination of events, and/or a trend that indicates an underlying problem. The implementation of this subject area should help minimize the recurrence of the problems

affecting Personnel Safety, Operational Safety, Regulatory & Environmental Compliance, Business Operations, Conduct of Operations, and/or areas of General Programmatic Breakdown.

Additionally, staff are encouraged to use causal analysis to better assimilate/communicate noteworthy management practices and uniquely successful projects/work activities for inclusion in the <u>Lessons Learned</u> Subject Area.

The purpose of a causal analysis is to identify the cause (or causes) of an issue of concern so that action can be taken to not only correct, but also prevent a similar recurrence. A causal analysis reviews the facts, establishes the chronology, and provides information that can prove beneficial to others. It is designed to be "fact finding," and not "fault finding" or "blame assignment." The facts documented through the causal analysis process can provide information pertaining to the

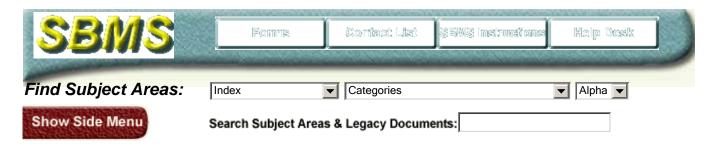
- identification of factors contributing to observed weaknesses or anomalous performance;
- dissemination of noteworthy management practices and uniquely successful projects/work activities;
- evaluation of the overall performance of management systems, programs, or processes; and
- determination of adherence to policies, standards, procedures, business, and operational goals.

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1. Analyzing the Issue of Concern

Effective Date: December 2003

Point of Contact: Quality Management Office

Applicability

This information applies to BNL staff and non-BNL staff who develop corrective and preventive actions.

Required Procedure

If the issue is supplier-related (procured goods or services), stop here. The causal analysis and the development of the corrective and preventive actions should be performed and documented by the supplier and provided to the responsible individual or designee. The Supplier Corrective Action Request (SCAR) Form can be used to document the supplier's analysis and actions.

A graded approach to analysis is used to ensure that the corrective actions are commensurate with the impact of the issue of concern and to effectively prevent its recurrence. Refer to the Corrective and Preventive Action Flowchart for an overview of this procedure.

| Review the issue and collect preliminary information as appropriate if not previously performed.

| Note: The information collected should include the conditions before, during, and after the event or condition was discovered; staff involvement (including actions taken); environmental factors; and other relevant details.

| Step 2 | The responsible individual reviews the exhibit Causal Analysis Methodology Selection Guidance and determines the appropriate method to use.

| Note: Causal Analysis Methodology Subject Matter Experts are available to

	racılıtate/assist in the implementation of causal analysis.
Step 3	Determine if a team is needed, based on the analysis methodology chosen. If a team is needed, select the team members.
	Note: Team members should be selected in order to compose a cross-functional team.
Step 4	Using the methodology selected, analyze the issue to determine the cause(s). Note: Select the Cause Codes provided in the exhibit Causal Analysis Tree in the Occurrence Reporting and Processing System (ORPS) Subject Area.
Step 5	Document the analysis as indicated in the subject area or process directing staff to this procedure. Where not indicated, document as directed by the responsible individual or manager.

References

Occurrence Reporting and Processing System (ORPS) Subject Area

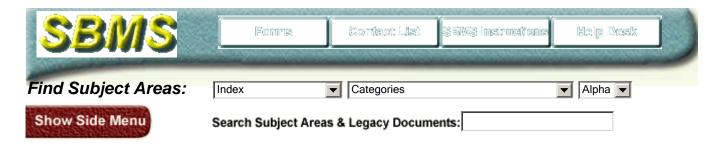
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2. Developing Corrective and Preventive Actions

Effective Date: December 2003

Point of Contact: Quality Management Office

Applicability

This information applies to BNL staff and non-BNL staff who develop corrective and preventive actions.

Required Procedure

Refer to the Corrective and Preventive Action Flowchart for an overview of this procedure.

Step 1	Based on the causes identified, develop corrective/preventive action(s) (see the Guidelines section below and the exhibit Corrective Action Selection Guidance) that adequately addresses the cause(s) of the issue of concern; dispositions the item, service, or process; and corrects the problem.
Step 2	Determine the degree of verification (i.e., closure and/or effectiveness) required. The degree of verification must be based on the risk associated with recurrence of the issue of concern as identified by the responsible individual or manager unless indicated by another subject area.
Step 3	Identify and process lessons learned (refer to the <u>Lessons Learned</u> Subject Area).
Step 4	Identify appropriate owners and due dates for the corrective/preventive actions. Obtain approval from the appropriate individual (i.e., line manager or responsible supervisor) for the proposed corrective and preventive actions and due dates.
Step 5	If you were sent to this subject area from another SBMS document and that document identifies action tracking and/or other requirements, return to that

	aucument. If not, proceed to step o.
Step 6	Distribute working copies of appropriate documents that define the corrective and preventive actions to staff assigned responsibility for planned corrective and preventive action(s), cognizant manager, and others, as required.
Step 7	Track the corrective actions to completion using the Family Assessment Tracking System (F-ATS) or other appropriate mechanism.

Guidelines

Corrective Action

The need to involve subject matter experts in determining appropriate corrective action should be considered. Use the following elements in developing the corrective action:

- reviews necessary by the organization that originally examined and approved the items or processes
- modifications of processes or procedures (see the <u>Internal Controlled Documents</u> Subject Area)
- recovery activities (for any items, services, or processes impacted by the issue)
- replacement demands
- training or education considerations
- coordination of implementation
- funding requirements
- milestones and completion date
- need for independent verification of the corrective action
- reinspection and testing of reworked, repaired, and replacement items to ensure that they meet original requirements or specified alternatives.

Preventive Action

To determine if a potential issue of concern exists in another area(s), the following questions should be asked:

- Where do we have similar requirements?
- Where do we perform similar tasks?
- Where do we perform similar processes?
- Where do we use similar documents?
- Where do we have similar materials, products, or services?
- Where do people perform similar functions?
- Where do we use similar equipment?

References

Family Assessment Tracking System (F-ATS)

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Internal Controlled Documents Subject Area

Lessons Learned Subject Area

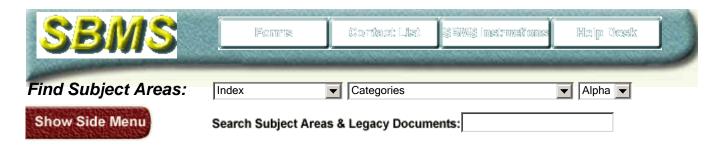
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Corrective and Preventive Action Flowchart

Effective Date: December 2003

Point of Contact: Quality Management Office

The Corrective and Preventive Action Flowchart is provided as a Word file.

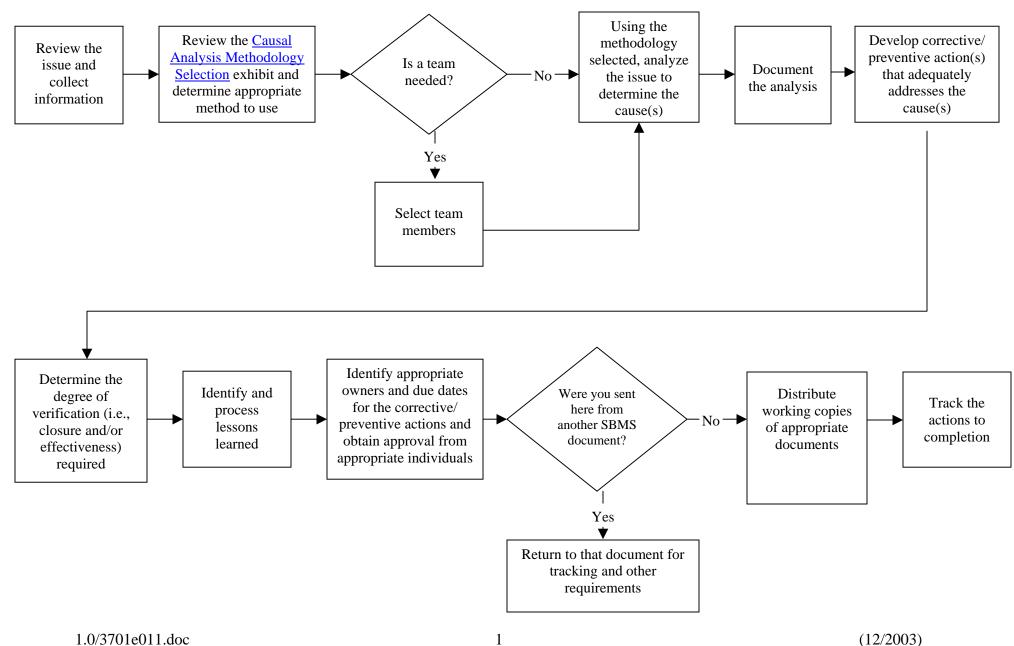
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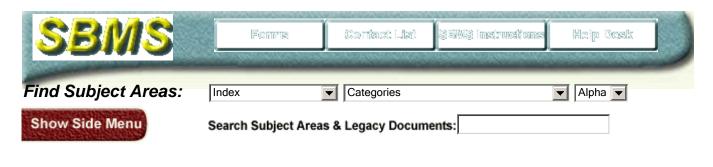
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Corrective and Preventive Action Flowchart





Causal Analysis Methodologies

Effective Date: December 2003

Point of Contact: Quality Management Office

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Causal Analysis Methodologies

This exhibit is not intended to be all-inclusive guidance. It is intended to give the user some basic information as to the purpose of the analysis, how it is applied, methods for conducting the analysis, necessary resources, and limitations. Where possible, examples pertinent to BNL operations are used to show typical contents and formats.

Five Whys

Purpose:

The Five Whys is a simple technique for determining the root cause(s) of an incident. It can also help provide an understanding of the relationship between different causes.

Application:

The Five Whys can be used for incident investigations, and proactive and reactive safety analyses. The technique can be utilized by an individual or a group, and is most useful when the problem involves human factors or interactions.

Methodology:

By repeatedly asking the question "Why?" a deeper understanding of a situation or concept will emerge. Begin the Five Whys technique by describing the specific problem or situation being analyzed, and gathering information. Ask why the problem or situation occurred. When an answer is found, ask "Why is this the case?" and continue asking the question why until the most basic cause is reached or there is no more information available. There is no requirement to the number of times that the question "why" must be asked, although five is the general rule. It is important to ensure that the questions are precise and the answers are factual.

Completeness:

If used properly, this technique should be efficient in determining the root cause.

Resources/Skills Required:

To work effectively and achieve optimal results with most problem solving teams, strong facilitation assistance is generally required. It is very important to keep the team on target and avoid diversions.

Limitations:

Beware: "If you don't ask the right questions, you don't get the right answers. A question asked in the right way often points to its own answer. Asking questions is the ABC of diagnosis. Only the inquiring mind solves problems." -- Edward Hodnett

References:

Causal Factors Analysis Training, Module 4: The Five Whys Technique, April 2001 DOE Office of Performance Excellence, Process Improvement Guide: Taking the Mystery Out of P.I.

Example:

Case Study of an Incident Involving the Improper Shipment of Hazardous Materials for Mid-America National Laboratory (MANL). (Also see <u>Events and Causal Factors</u> <u>Analysis (ECFA)</u> in this exhibit for the facts and an ECFA on this same scenario)

The Five Whys

Why did the shipping violations occur?



The samples were transported to Laboratory A incorrectly (noncompliant with DOT regulations)

Why were samples transported incorrectly?



The samples were packaged incorrectly and mislabeled

Why were the samples packaged incorrectly and mislabeled?



The employee performing the packaging and shipping was not properly trained for this work

Why was the employee not properly trained?



The training requirements were not incorporated into the work process



Why weren't the training requirements incorporated?



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Brainstorming

Purpose:

Brainstorming is a technique for gathering ideas, in a short period of time. Ideas are generated, clarified, evaluated, supported by data if necessary, and opportunities for improvement are identified.

Application:

Brainstorming is a simple technique that can be used for low-level, non-reportable incidents that do not require a systematic approach of analysis.

Methodology:

Brainstorming sessions should have a facilitator to keep the process flowing and record all ideas. Before a brainstorming session begins, rules should be agreed upon regarding the format of the session. Decide on whether the session will be; "structured," with the participants taking turns sharing ideas in an orderly fashion, "unstructured," with ideas being shared as they are thought of, or a combination of both.

The brainstorming session should include 3 phases:

- Idea generation
- Idea clarification
- Idea evaluation

Idea generation:

Define the issue or situation, and ensure all participants agree with the definition. Allow time for the participants to think about the issue or situation. As ideas are exchanged they should not be discussed or criticized. All ideas should be recorded so they are visible, making sure the speaker's words are used, to ensure there is no interpretation. Participants can build on other ideas presented.

Idea clarification:

When all ideas are exhausted, the facilitator should review each idea and clarify them, to ensure that all participants understand them.

Idea evaluation:

The list of ideas should be reviewed, and duplicate or irrelevant material eliminated. Ideas that seem the most promising and valid should be refined.

When the corrective actions are being selected (by appropriate personnel) each idea should be made clear and the input from each participant reviewed. The ideas/solutions with the most impact should be considered first. The knowledge, education, and

experience of the Brainstorming session participants, should be accumulated to assist in selecting the best actions.

To evaluate the results of the idea portion of the Brainstorming session, a criteria grid can be developed:

Idea or Solution	Time to Solve (in months)	Impact High Medium Low	Cost High Medium Low	Multiple Organization Involvement To Solve Yes or No	Will Management Support Solution Yes or No

Once corrective actions have been implemented, feedback should be provided to the participants of the Brainstorming session, to endorse participation for future sessions.

Brainstorming can be based on opinions, so it is important to support ideas with data when necessary. It is also important to check to ensure that no information was overlooked.

Completeness:

The level of completeness depends on the experience of the facilitator and the level of participation from the group.

Resources/Skills Required:

The Brainstorming technique requires no previous experience. Team member's chosen should be those who are willing to speak out. The facilitator must ensure that there is no criticism of any idea from any member of the group. Criticism inhibits the free flow of ideas.

Limitations:

Due to the rather unstructured nature of the Brainstorming technique, results can be incomplete, and key elements may be overlooked.

References:

DOE Office of Performance Excellence, Process Improvement Guide: Taking the Mystery Out of P.I.

QAM16-03, Reactor Division Root Cause Procedure

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Expert Judgment

Purpose:

Judgment plays a key role in analyzing root causes of unanticipated events/conditions. Expert Judgment is implicit in all of the causal analysis methodologies delineated. However, the analyst's education and experience form the decision-making framework when judgment is used explicitly to determine the most probable cause, and when a specific expertise is deemed enough for making root-cause determinations.

Application:

Engineering Judgment is an informal technique that can be used for low-level, non-reportable incidents that do not require a systematic approach of analysis. The analyst compares the situation to other events in terms of similarities and differences, evaluates the likelihood of perceived accident scenarios that could have led to the "top event", and then decides on the most likely scenario, and finally root cause(s).

The responsible manager may consult either an analyst known to them, an analyst recommended by someone else, or a <u>Causal Analysis Methodology Subject Matter Expert</u> (<u>SME</u>) identified in SBMS. The manager may also be qualified to serve as the expert for this methodology.

Methodology:

The responsible manager provides the analyst with the necessary information (as determined by the analyst) concerning the adverse events or conditions. Experience and skills are used to analyze the failed system, as it is, conceive as to how it might be, and then ascertain the most likely sequence of events leading to the unwanted event. The results of the logical thought processes of analysis and synthesis are compared to the situation that has occurred to determine the nature of the root cause(s) and to identify appropriate corrective actions.

Completeness:

Expert Judgment is not a formal process. The level of completeness depends on the experience/education of the analyst, the complexity of the system, and knowledge of the system failure under investigation.

Resources/Skills Required:

The expert must have an appropriate knowledge base and experience relevant to the adverse event or condition.

Limitations:

The responsible manager must select an analyst with appropriate knowledge and experience. An important factor in using Expert Judgment to determine root cause(s) is the value structure of the analyst. Also, the analyst can only guess concerning the human responses that might be stimulated by other system failures within the accident sequence. There for, it must be recognized that this method is limited to a single person's judgment.

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Events and Causal Factor Analysis (ECFA)

Purpose:

Events and Causal Factor Analysis (ECFA) is a method of identifying causes, by correctly establishing the chronology of all events and conditions leading to and following an incident. The ECFA is used to

- Organize, illustrate, and present data
- Help derive causal factors from specific event chains
- Show relationships among events and conditions
- Identify information gaps
- Provide a guide for reporting

Application:

Events and Causal Factor Analysis is a tool for multi-faceted problems with a long or complex causal factor chain. This technique is used to determine how and when a task was performed, to identify problems in human-factors design, and to identify discrepancies in procedural steps or training. For complex problems it can be a time consuming process that is most effective when prepared by someone familiar with the process. The ECFA can be used as a stand-alone technique or combined with other analytical techniques (e.g., see the <u>Guidance on Barrier Analysis</u> and the <u>Guidance on Change Analysis</u> exhibits in the <u>Hazard Analysis</u> Subject Area, and the <u>Five Whys</u>), to facilitate in determining root causes.

Methodology:

To correctly establish the chronology of events surrounding an incident, an understanding of the intended outcome should be established. Obtain preliminary information regarding the actions being performed or the conditions present during the incident. Obtain any relevant procedures, drawings, diagrams, log books, photographs, etc. Interview personnel who were involved in the incident and also personnel who normally perform the task, in order to obtain an understanding of how the task should be performed. Create a guide of how the task should be carried out, identifying the steps, key indicators and displays.

Select personnel who usually perform the task and ask them to demonstrate the task as it is normally carried out. On the guide that was created, check off each step, indicator, or control as it occurs, and note any discrepancies or problems. Summarize any problem areas that were noted. Reenactment of the task or situation will contribute to overall comprehension of the situation.

A chart is created to consolidate and organize all information regarding the events and conditions surrounding the incident. (Post-It notes are useful when creating the initial chart because they are easy to re-arrange.) Identify the incident and all of the actions/events that occurred prior to the incident. Map out all of the actions/events in squares, in chronological order. For each event identify conditions that led to that event or contributed to the situation. Map these conditions in ovals underneath or above the appropriate events (squares). The incident will be distinguished in the sequence by a diamond shape. Continue mapping events (and their conditions) that occurred after the incident until stability was reached.

Event: Something of significance that happened at a specific point in time. Example: radioactive material found in ABC Laboratory; corrective actions not completed on time (must have a noun and verb, specific time and place, and source of data).

Condition: state or circumstance relative to the event. Examples: 90 degree temperature; worker unaware of safety procedure; manager did not understand responsibility for action.

Once all the events and conditions are mapped, begin the analysis to identify the "causal factors" of the incident. To accomplish this, first evaluate each event and determine its significance. Significant events are those that meet the following criteria;

- The incident would not have occurred if the event had not occurred
- The event deviated from what was planned or intended
- The event had unwanted consequences

The "causal factors" or conditions of the incident will lie in the ovals. They are identified by determining if the absence of that factor would have reduced the likelihood that an incident would have happened or would have reduced the severity of the incident. When identified change the symbol from an oval to a hexagon.

Events and Causal Factors Chart Symbols/Suggested Format

1.	Event Enclosures Events should be enclosed i	n rectangles, and conditions in	ovals.
2.	Event Connections Events should be connected	by solid arrows.	
3.	Conditions Connections Conditions should be conne by dashed arrows.	ected to each other and to events	
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4. Basis for Events and Conditions

Each event and condition should be either based upon valid factual evidence or be clearly indicated as presumptive by dashed line rectangles and ovals.



5. Depiction of Sequence of Events

The primary sequence of events should be depicted in a straight horizontal line (or lines in confluent or branching primary chains) with events joined by bold printed connecting arrows. Events should be arranged chronologically from left to right leading up to the incident depicted by a diamond. Events typically continue after the incident until stability is reached.



6. Identification of the Causal Factors

Once causal factors are identified the ovals can be changed to hexagons for a visual representation of the causal factors.

Completeness:

Results are directly proportional to the extent that the person or team has defined the formal requirements for the analysis. Since the technique may be time consuming, its thoroughness is also related to the man-hours expended during the analysis. The Event and Causal Factors Analysis does not produce quantitative results unless other quantitative techniques such as Fault Tree Analysis (see the <u>Guidance on Fault Tree Analysis</u> exhibit in the <u>Hazard Analysis</u> Subject Area) are integrated into the overall effort.

Resources/Skills Required:

The Event and Causal Factors Analysis technique may require one or more trained/experienced personnel from several different disciplines with varying experience.

The technique is not difficult to learn and lends itself well to an experienced analyst walking an inexperienced group through the process.

Limitations:

Care must be taken not to limit analysis to merely addressing the symptoms of a problem. The symptoms are sometimes causes in themselves, however, they are often only indications that other factors must be pursued to find the underlying causes.

References:

DOE-76-45/14 SSDC-14 Revision 2, Events and Causal Factors Charting. May 1993 Causal Analysis Pilot Training Course for BNL, (Battelle Memorial Institute, April 25, 2001)

Examples/Format

Example 1 (simple)

Accident Description. Ajax Construction Company was awarded a contract to build a condominium on a hill overlooking the city. Prior to initiation of the project, a comprehensive safety program was developed covering all aspects of the project. Construction activities began on Monday, October 4, 2002, and proceeded without incident through Friday, October 8, 2002, at which time the project was shut down for the weekend.

At that time, several company vehicles, including a 2-1/2 ton dump truck, were parked at the construction site. On Saturday, October 9, 2002, a nine-year-old boy who lives four blocks from the construction site, climbed the hill and began exploring the project site. Upon finding the large dump truck unlocked, he climbed into the cab and began playing with the vehicle controls. He apparently released the emergency brake and the truck began to roll down the hill. The truck rapidly picked up speed. The boy was afraid to jump and did not know how to apply the brakes. The truck crashed into a parked auto at the bottom of the hill. The truck remained upright, but the boy suffered serious cuts and lacerations and a broken leg. The resultant investigation revealed that, although the safety program specified that unattended vehicles would be locked and the wheels chocked, there was not verification that these rules had been communicated to the drivers. See the Construction Company Events and Causal Factor Chart Example exhibit.

Example 2 (complex)

Summary: On July 31, 2000, in the course of carrying out a characterization and monitoring project ("the Project") at Mid-America National Laboratory (MANL), operated by Acme Consulting Engineers and Scientists, Inc. (ACES), a contractor reporting to ACES incorrectly shipped radioactive samples to an analytical laboratory. The shipment contained radioactive material, but was improperly offered for transport and transported via public roads as un-declared hazardous material, resulting in probable violation of U.S. Department of Transportation regulations. The laboratory notified the

ACES-MANL Sample Management Office that the samples were not compliant with U.S. DOT shipping requirements. As required, ACES notified the local DOE Operations Office, DOE-MA. The notifications prompted responses, including and incident investigation of this event by ACES-MANL.

Project Description: The scope of this Project was to install groundwater wells and conduct subsurface soil sampling. Preceding the shipment, samples were being extracted from borings around a low-level liquid waste tank. ACES had overall management of the Project and a subcontract was in place with Brilliant Technologies to obtain analytical and geo-technical analyses and to manage field sampling and drilling activities.

Facts: Project Planning

- Initial project planning began on June 30, 2000.
- A series of project meetings were held between July 3 and July 28, 2000.
- DOE-MA, ACES-MANL and Brilliant Technologies were represented by senior management at each meeting.
- A project that involved soil characterization, sampling, and transportation was completed by MANL in April 1999.
- The lessons learned from the April 1999 project were not incorporated into the work package for the work prior to the event.
- Both MANL and DOE-MA had dedicated line managers overseeing this project.
- The project had an ample budget to ensure swift and effective completion.
- The scope of work for the project was written in general terms because it was viewed as a routine activity.
- Specific responsibilities for preparing and transporting shipments were not discussed; however, meeting attendees agreed they understood their respective roles and responsibilities regarding this project since it was viewed as a routine activity.
- The need for training, with respect to the packaging and transportation of hazardous material, was not integrated into the work plan; therefore, the training did not occur.

Lessons Learned

- Data was found that indicated that six previous events involving DOT non-compliant hazardous materials shipments from MANL had occurred within the last twelve months. Four of these events involved the incorrect characterization of materials, and five of the incidents listed inadequately trained personnel as a contributing cause.
- Lessons learned from these incidents were not an agenda item at any of the project planning meetings.
- A review of the ORPS data for the last five years indicated the MANL reported 18 previous transportation occurrences involving hazardous materials.
 ("Management systems" were identified as the root cause for half of these occurrences.)
- Data revealed that MANL has 142 outstanding corrective actions.

 The system to resolve and close corrective actions is currently under revision to develop a formalized tracking process.

DOE-MA

- DOE-MA conducted a management assessment of ACES-MANL on July 17, 2000
- The management assessment focused on deficiencies regarding the implementation of an integrated safety management system at MANL.
- The working relationship between DOE-MA and MANL is generally cooperative and pleasant.

ACES-MANL

- ACES has managed MANL for 12 years.
- The MANL Director retired July 25, 2000, after a series of reports and memos from DOE-MA were released regarding the ongoing lack of effective corrective action implementation and performance measures for a multitude of deficiencies at the laboratory.
- The MANL corrective action tracking and resolution group was downsized two years ago due to budgetary constraints.
- Personnel records revealed that staff associated with the Project were appropriately trained and qualified.
- An ACES management assessment was completed on July 17, 2000. Deficiencies noted included references to continuous improvement and work controls. The assessment concluded ACES-MANL management of subcontractors was adequate.

Brilliant Technologies

- Brilliant Technologies is a five-year-old environmental consulting firm.
- They have worked as a subcontractor at MANL for the last three years.
- Brilliant Technologies has had a high attrition rate during the last year.
- Budget cuts have caused the Brilliant training budget to be reduced by one-third in the past year.
- Brilliant Technologies is simultaneously managing the field aspects of a start-up environmental restoration project that began June 1, 2000.
- Brilliant Technologies' transportation safety specialist was not involved in this project.

Work Planning

- A project plan was approved by DOE-MA and ACES-MANL on July 22, 2000.
- The project work plan was developed without a hazards analysis; therefore, many of the hazards were not identified in the work plan.
- Some of the workers with Brilliant Technologies were working on both contracts.
- Packaging and transportation of samples were not identified as potential hazards.

No formal surveillance of audit schedule was developed for the project.

Staffing and Qualifications

- The shipment of hazardous material was performed by personnel not trained in DOE requirements.
- Employees performing material classification and characterization were appropriately trained.
- Employees performing packaging, shipment preparation, and transport were not properly trained for these functions.

Compliance with Regulations

- The soil samples shipped July 31, 2000, failed to comply with the Federal and State requirements for packaging, offering for transportation, and transporting hazardous materials.
- Since the material was improperly identified and classified under DOT regulations,
 - □ The material was improperly packaged.
 - □ The packages were not properly marked and labeled.
 - □ Required shipping documentation was not prepared.
 - □ The vehicle transporting samples to Lab A was not properly placarded.
 - □ The driver of the vehicle driven to Lab A was not properly licensed for transporting this material.
 - □ An emergency contact number was not provided and manned while all the samples were in transit.
 - Dose rate surveys to ensure compliance with regulations were not performed prior to the shipments being released for offsite shipment.

See the Shipping Violation Events and Causal Factor Analysis Chart Example exhibit.

Causal Factor Determination

- A. Lessons learned from the April 1999 activity were not considered or incorporated into the current project.
- B. Hazards associated with the sampling, packaging, and shipping of hazardous materials were not identified.
- C. The training requirements were not identified or integrated into the work process.
- D. The scope of work was not sufficiently detailed for the risks associated with this project.
- E. The MANL lessons learned/corrective action-tracking program is not formalized, and the continuous improvement program is not adequate.
- F. The work controls associated with this project are not sufficient.
- G. Hazards associated with the project were not identified or analyzed during the work planning process.
- H. Hazards associated with the sampling, packaging, and shipping of hazardous materials were not identified at the commencement of work.

- I. An ESH professional (transportation safety specialist) was not involved in the work planning and therefore not present at the drilling site.
- J. Samples do not comply with the Federal and State requirements governing the shipment of hazardous materials.
- K. The employee performing the packaging and shipping was not properly trained for this function.
- L. The employee performing the packaging and shipping did not have competencies commensurate with responsibilities.

Root Cause Discussion (see the **Five Whys** analysis on this same scenario)

Work process controls were inadequate because hazards were not identified or analyzed and the scope of work was not sufficiently detailed to accommodate the risks involved with the shipment. The work process was performed without a proper and sufficient hazards analysis, consideration of DOT requirements (resulting in an untrained worker), the development of an audit schedule, or the use of a transportation safety specialist. Therefore, the transportation and packaging requirements were not incorporated into the project plan or communicated to the workers performing the sampling, packaging and shipping.

Feedback and improvement were inadequate because there was insufficient follow-up for previous corrective actions on similar deficiencies, and lessons learned had not been incorporated into the shipment involving the hazardous material. MANL management failed to incorporate lessons learned from previous similar activities and many outstanding corrective actions. Doing so may have alerted employee and subcontractor employees to the hazards associated with the sampling, packaging and shipping activities. MANL has been cited in a DOT-MA assessment for their lack of follow-up and continuous improvement.

Management Oversight and Risk Tree (MORT) Analysis

MORT Analysis is a graphic checklist that provides a systematic method for determining the causes and contributing factors of an incident. It contains a series of questions regarding a system's operating factors and management control factors. It is particularly useful in preventing oversight of the identification of causal factors. MORT is a technique that can also be used to evaluate the quality of a proposed or existing system.

MORT Analysis is a complex and time-consuming technique for complex incidents that should be conducted by a trained and qualified Causal Analysis Methodology Subject Matter Expert (SME).

Contact the <u>Causal Analysis Methodology Subject Matter Expert (SME)</u> for inquiries on MORT Analysis.

References:

DOE-NE-STD-1004-92, DOE Root Cause Analysis Guidance Document, February 1992 ACC-INV 103, System Safety Development Center User's Guide and Cut Sheets for The Management Oversight and Risk Tree

TapRooT®

The TapRooT® System is a systematic tool used to determine the root cause(s) of equipment and human performance problems. The focus is on the system (the way that the work is performed), not the individual. The analyst, with a small team, objectively looks at the facts, identifies the problem, and goes through a systematic process to find the root causes. Software can be utilized that documents and assists in the causal analysis process and the creation of corrective actions.

The TapRooT® technique should be used for complex problems/issues. It can be a time-consuming process that should be conducted by a trained and qualified Causal Analysis Methodology Subject Matter Expert (SME).

Contact the <u>Causal Analysis Methodology Subject Matter Expert (SME)</u> for a TapRooT® analysis.

References:

TapRooT® The System for Root Cause Analysis, Problem Investigation, and Proactive Improvement by Mark Paradies and L. Unger (System Improvements Inc., 2000)



Causal Analysis Methodology Selection Guidance

Effective Date: December 2003

Point of Contact: Quality Management Office

The Causal Analysis Methodology Selection Guidance is provided as a Word file.

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Causal Analysis Methodology Selection Guidance

METHODOLOGY	WHEN TO USE	ADVANTAGES	DISADVANTAGES
See <u>Guidance on What-</u> <u>If Analysis</u> in the <u>Hazard Analysis</u> SA. (Low complexity-level methodology)	Use for simple issues. Events/conditions where causes are somewhat evident.	Simple; User-friendly; Cost effective.	Not normally appropriate for complex issues. Good only for relatively simple systems; it will not usually pick up multiple failures or synergistic effects.
See <u>Five Whys</u> in the <u>Causal Analysis</u> <u>Methodologies</u> exhibit. (Low complexity-level methodology)	Use for simple issues. Events/conditions where causes are somewhat evident.	Simple to use. Can determine relationship between different root causes.	No real structure to questioning beyond why did this happen.
See <u>Brainstorming</u> in the <u>Causal Analysis</u> <u>Methodologies</u> exhibit. (<i>Low complexity-level methodology</i>)	When several system experts/operators are available to assist.	Simple to use. Does not require a lot of time. Cost effective.	Based on experience and opinions of team members. May be swayed by dominant participant. Lacks specific structure.
See <u>Expert Judgment</u> in the <u>Causal Analysis</u> <u>Methodologies</u> exhibit. (<i>Low complexity-level methodology</i>)	When specific expertise is enough to make a root cause determination.	Quick and cost effective.	Limited to a single person's judgment.
See <u>Guidance on</u> <u>Barrier Analysis</u> in the <u>Hazard Analysis</u> SA. (Moderate complexity- level methodology)	Use to identify barrier and equipment failures and procedural or administrative problems.	Provides a systematic approach. Simple; Visual.	Requires familiarity with the process to be effective (works well in conjunction with ECFA).
See <u>Guidance on</u> <u>Change Analysis</u> in the <u>Hazard Analysis</u> SA. (Moderate complexity- level methodology)	Use when cause is obscure. Especially useful in evaluating equipment failures where changes in maintenance, procedures, personnel, and design precipitated incident.	Simple 6-step process. Can be focused on part of a system.	Limited value because of danger of accepting wrong, "obvious" answer.
See Events and Causal Factors Analysis (ECFA) in the Causal Analysis Methodologies exhibit. (Moderate complexity- level methodology)	Use for multifaceted problems with long or complex causal factor chain. Use when sequence of discrete events lead to incident.	Provides a visual display of analysis process. Identifies probable contributors to each event/condition.	Time-consuming and requires familiarity with process to be effective.
See <u>Guidance on Fault</u> <u>Tree Analysis</u> in the <u>Hazard Analysis</u> SA. (High complexity-level methodology)	Use for complex issues where a systemic approach is necessary and documentation is required. For example: failure of cryogenic systems, electrical	Produces tabulated hierarchy of causes with specific identification of root cause(s).	May require significant training for proper use and interpretation or use of a trained facilitator.

	systems, and control systems.		
See Management Oversight and Risk Tree (MORT) Analysis in the Causal Analysis Methodologies exhibit. (High complexity-level methodology)	For complex system failures and/or serious injury/fatality or high-value property damage.	Process is extremely robust and involves consideration of all potential causes. Identifies management system weaknesses.	May require significant training for proper use and interpretation or use of a trained facilitator. Very time/resource intensive.
See <u>TapRooT®</u> in the <u>Causal Analysis</u> <u>Methodologies</u> exhibit. (High complexity-level methodology)	For complex system failures and/or serious injury/fatality or high-value property damage.	Process is extremely robust and involves consideration of all potential causes. Identifies management system weaknesses.	May require significant training for proper use and interpretation or use of a trained facilitator. Very time/resource intensive.

Causal analysis may be implemented by using low-complexity level methods to determine if the assumption of isolated (nonprogrammatic) noncompliance is valid. The responsible individual or designee may determine that additional, moderate-complexity level analysis may be necessary because of potential for programmatic impact. If programmatic noncompliance is evident, high-complexity level analysis is recommended. The analytical methodologies noted in the chart are only recommended. The responsible individual or designee may decide to use a higher complexity level methodology for a lower level noncompliance or the lower complexity level methodology for the higher level noncompliance. The Line Manager may enlist the support of personnel from other organizations who are trained and/or experienced in causal analysis methodologies, to help facilitate the analysis.

Ultimately, the responsible individual must achieve a comfortable level of certainty that causes have been correctly determined.



Construction Company Events and Causal Factor Chart Example

Effective Date: December 2003

Point of Contact: Quality Management Office

The Construction Company Events and Causal Factor Chart Example is provided as a <u>PDF</u> file.

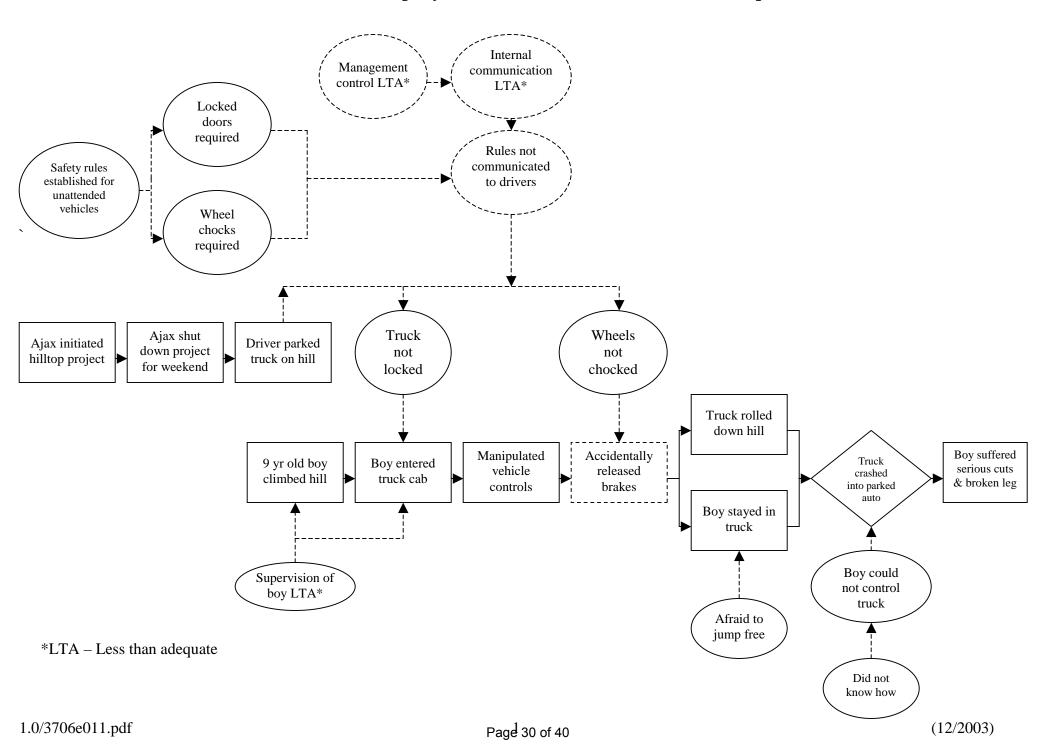
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Construction Company Events and Causal Factor Chart Example





Corrective Action Selection Guidance

Effective Date: December 2003

Point of Contact: Quality Management Office

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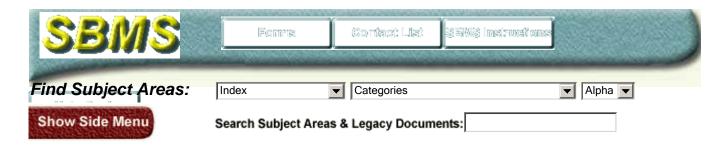
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Corrective Action Selection Guidance

LEVEL OF EFFECTIVENESS	CORRECTIVE ACTION TYPE	EXAMPLES OF IMPLEMENTATION	ADVANTAGES	DISADVANTAGES
High	Physical	-Equipment and Engineering Design -Machine Guards -Separation -Locks -Walls -Shielding -Shut Valves -Warning Devices	-Best at minimizing human error -No learning curve -Difficult to bypass or work around -Only defensible choice as single barrier -Some small investments with big returns	-Requires investment of real dollars -May take time to construct/implement -May require maintenance
Moderate	Administrative	-Policies -Procedures -Technical Work Documents -Checklists -Warning Signs/Postings -Personal Protective Equipment	-Basis for consistency in performance -Good return for investment -Key for defense in depth	-Subject to the organization's culture regarding complianceRequires additional resources to ensure accountability -Significant learning curve for change of behavior
Low	Management	-Training -Supervision -Line Management Oversight	-Training essential to invoke procedures -Mentoring key to changing behavior -Management presence reinforces (and enforces) accountability	-Requires change in culture -Long learning curve for training

Note: Each of these actions becomes more effective when used with multiple barriers (defense in depth).



Shipping Violation Events and Causal Factor Analysis Chart Example

Effective Date: December 2003

Point of Contact: Quality Management Office

The Shipping Violation Events and Causal Factor Analysis Chart Example is provided as a PDF file.

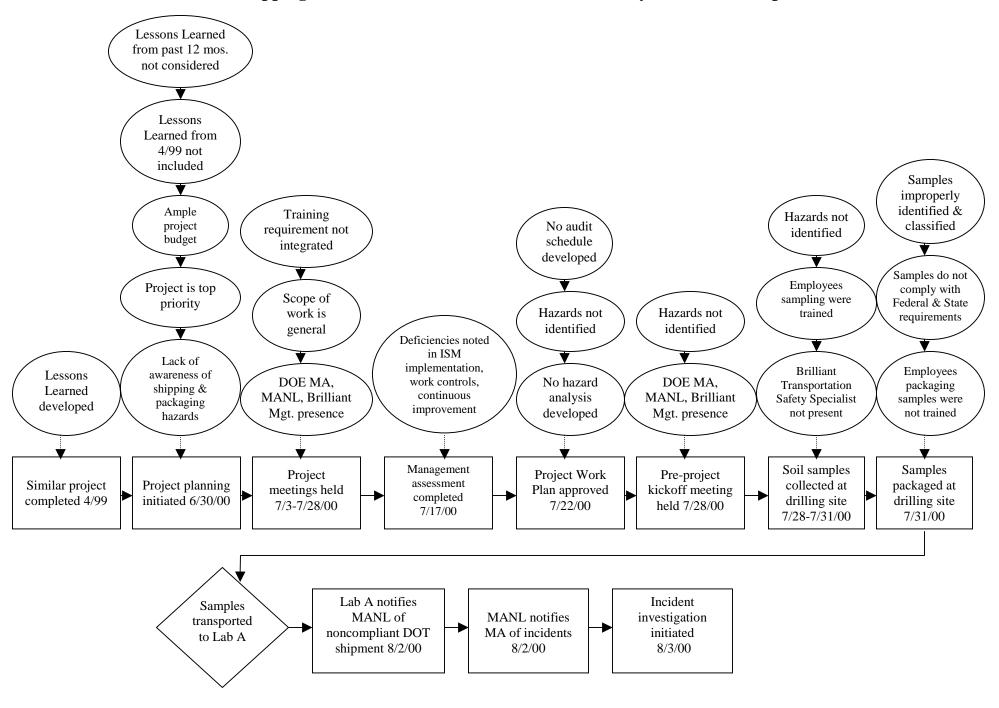
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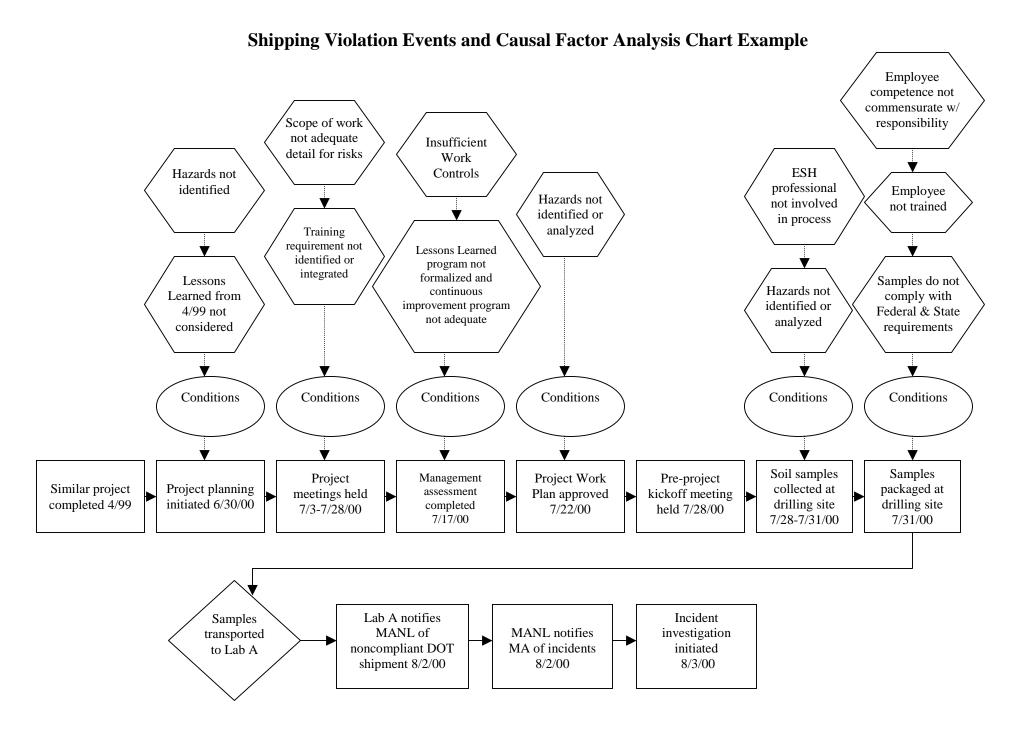
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Shipping Violation Events and Causal Factor Analysis Chart Example







Supplier Corrective Action Request (SCAR) Form

Effective Date: December 2003

Point of Contact: Quality Management Office

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Brookhaven Science Associates U.S. Department of Energy

<u>Supplier Corrective Action Request (SCAR) Form</u> SCAR #: <vendorid+mmyy+##>

BNL SCAR Originator:	Em	ail:	Date:		
SUPPLIER NAME:		SUPPLIER	CODE / ID#:		
SUPPLIER CONTACT:		ITEM/SERV	ITEM/SERVICE DESC:		
P.O./CONTRACT #:		PO_LINE IT	PO_LINE ITEM:		
	oplicable, complete QTY I following:	RECEIVED	QTY INSPECTED	QTY DEFECTIVE	
PROBLEM DESCRIPTION:					
Reference Documentation:					

Supplier Instructions: Please complete the following Sections 1 and 2 and return to the BNL SCAR Originator via e-mail within 15 business days.

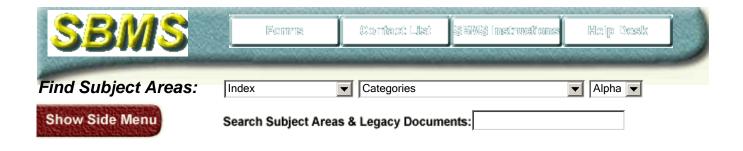


1. ROOT CAUSE ANALYSIS

problem description, drill down as far as possible to determine true root cause): Why: Why: Why: Why: Why: Root Cause(s): 2. CORRECTIVE / PREVENTIVE ACTION PLAN Action(s) taken to correct current condition: Action(s) Taken To Prevent Recurrence: Responsible Party: **Effective Date:** Comments: **Contact Name:** E-mail: Title: Phone: FAX: Date: 3. BNL APPROVAL **Date Received By BNL: SCAR Originator Approval:** ☐ Yes ☐ No IF No, Why/Action to be taken: Date:

A recommended method for determining the root cause is the "5 Why" Method (starting with the

1.0/3705e011.doc 2 (12/2003)



Definitions: Corrective and Preventive Action

Effective Date: December 2003

Point of Contact: Quality Management Office

Term	Definition
causal analysis	Causal analysis refers to a methodology used to determine the most probable cause(s) of an undesired event, resulting in long-term corrective action(s) and the possibility of preventing event recurrence.
causal factor	An event or condition that either caused the occurrence under investigation or contributed to the unwanted result. If it were not for this event or condition, the unwanted result would not have occurred or would have been less severe.
condition	Any as-found state, whether or not resulting from an event, that may have adverse safety, health, quality assurance, security, operational, regulatory, or environmental implications. A condition is usually programmatic in nature, for example • An error in analysis or calculation; • An anomaly associated with design or performance; or • An item indicating a weakness in the management process are all conditions.
contributing factors	A factor that contributed to an occurrence but by itself would not have caused the occurrence. For example, in the case of a leak, a contributing factor could be lack of adequate operator training in leak detection and response, resulting in a more severe event than would have otherwise occurred. In the case of a system misalignment, a contributing factor could be excessive distractions to the operators during shift change, resulting in less-than-adequate attention to important details during system alignment.
corrective action	A purposeful change implemented to eliminate a specific cause and prevent recurrence.
	Oursetting significant and seed that the them are 7s as also basely

event	Sometning significant and real-time that nappens (e.g., pipe break, valve failure, loss of power, environmental spill, earthquake, tornado, flood).
graded approach	A process for determining that the appropriate level of analysis, controls, documentation, and actions necessary are commensurate with an item's or activity's potential to • Create an environmental, safety, or health hazard; • Incur a monetary loss due to damage, or to repair/rework/scrap costs; • Reduce the availability of a facility or equipment; • Adversely affect the program objective or degrade data quality; • Unfavorably impact the public's perception of the BNL/DOE mission.
lessons learned	A "good work practice" or innovative approach that is identified and shared, or an adverse work practice or experience that is shared to avoid recurrence. Lessons learned is text that documents changes in activities or procedures made because of an event considered significant enough to become part of the corporate memory. This event may have either a positive or negative connotation.
nonconformance	A deficiency in a characteristic, documentation, or procedure that renders the quality of an item or service unacceptable or questionable. Examples of nonconformances include physical defects, test failures, incorrect or inadequate documentation of data, or deviation from prescribed processing, inspection, or test procedures, including the following • A failure to follow established procedures; • A failure to develop, document, or implement any required element of a program (i.e., Quality Assurance, Conduct of Operations, Maintenance or Environmental Management System) or activity established by mutual agreement with the client; • A situation in which the quality of an activity or document is questionable (e.g., where the stated or implied purpose has not been met, or where insufficient information exists to support the results that have been produced); • Not adhering to legal or other requirements, including administrative ones, such as labeling, records, or other

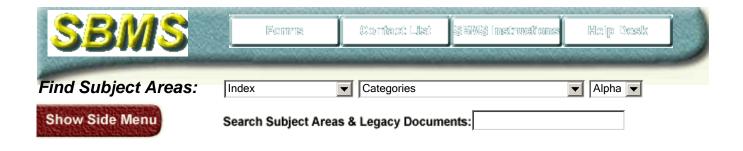
	documentation requirements.
occurrence	An event or a condition that adversely affects, or may adversely affect, DOE or contractor personnel, the public, property, the environment, or the DOE mission. Events or conditions meeting the criteria threshold identified in the DOE Occurrence Reporting Program.
preventive action	Long-term cost/risk-weighted action taken to prevent a problem from occurring, based on an understanding of the product or process.
	Preventive action will address inadequate "conditions" which may produce nonconformances.
Responsible Manager	A Responsible Manager (e.g., Department Chair/Division Manager) is responsible for preparing reports, obtaining report reviews and approvals, and assigning responsibility for causal analysis and implementation of corrective actions.
root cause	The cause that, if corrected, would prevent recurrence of this and similar occurrences. The root cause does not apply to this occurrence only, but has generic implications to a broad group of possible occurrences, and it is the most fundamental aspect of the cause that can logically be identified and corrected. There may be a series of causes that can be identified, one leading to another. This series should be pursued until the fundamental, correctable cause has been identified. For example, in the case of a leak, the root cause could be management not ensuring that maintenance is effectively managed and controlled. This cause could have led to the use of improper seal material or missed preventive maintenance on a component, which ultimately led to the leak. In the case of a system misalignment, the root cause could be a problem in the training program, leading to a situation in which operators are not fully familiar with control room procedures and are willing to accept excessive distractions.

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Revision History: Corrective and Preventive Action

Point of Contact: Quality Management Office

Revision History of this Subject Area

Date	Description	Management System
August 2004 Minor Rev. 1.1	The Environment, Safety, Health and Quality (Tier I) Inspections Subject Area replaces ES&H Standard 1.2.0, Departmental Environment, Safety & Health Inspections; the Quality Programs & Services Office is now the Quality Management Office.	Quality Management
December 2003	This subject area provides Laboratory-wide procedures for developing corrective and preventive actions to address identified issues of concern based on causal analysis. An issue of concern may be a nonconformance, assessment finding, one significant event, a combination of events, and/or a trend that indicates an underlying problem. This subject area includes a graded approach for conducting causal analysis using suggested methodologies. The graded approach is based on the significance associated with the issue of concern, or as required by the governing subject area. This subject area replaces IO-SOP-11, Conducting Causal Analysis For PAAA Noncompliances, Rev. 1.	Quality Management

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